Ad hoc Group on the evaluation of bovine spongiform encephalopathy (BSE) risk status of Members

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Table of Contents

List of Annexes

A meeting of the *ad hoc* Group on the evaluation of bovine spongiform encephalopathy (BSE) risk status of Members (hereafter the Group) was held from 1 to 4 October 2024.

1. Opening

Dr Min-Kyung Park, Head of the Status Department, on behalf of Dr Montserrat Arroyo, Deputy Director General for International Standards and Science of WOAH, welcomed the Group. She thanked the experts for their availability and contribution to the work of WOAH and extended her appreciation to their employers for allowing their participation in this meeting. Dr Park acknowledged the amount of work before, during and that would be done after the meeting in reviewing the dossiers and writing the report. Dr Park thanked the Group for its commitment and support to WOAH in fulfilling the mandates given by Members.

Dr Park highlighted the importance of the quality of the report to be scrutinised by Members before adopting the proposed list of countries/zones with a BSE risk status. She also encouraged the Group to continue providing detailed feedback to Members with a negative outcome to support them in identifying the main gaps and points for improvement to achieve their desired BSE risk status, as well as providing informative recommendations to those Members with positive outcomes for further improvement in maintenance of their BSE risk status.

Dr Park highlighted that this was the first year that the Group would be assessing applications based on the revised BSE requirements of the *Terrestrial Animal Health Code* (*Terrestrial Code*) adopted in May 2023, thus the quality of the discussions and the report were particularly important, as standard setting for the coming years. Additionally, as the preparatory working documents for the experts to note their assessments had been updated according to the newly adopted BSE standards, the Group was invited to provide its feedback on them. The Group was also invited to provide inputs on the new BSE annual reconfirmation form that Members will be using for the first time during the November 2024 campaign.

The Group and WOAH welcomed Dr Ángel Ortiz-Peláez, Dr Fernanda Mejía-Salazar, Dr Amie Adkin and Dr Yoshifumi Iwamaru as new members of the Group.

2. Adoption of the agenda and appointment of Chairperson and Rapporteur

Dr Lesley van Helden chaired the Group. Dr Fernanda Mejía-Salazar acted as rapporteur, with support from the WOAH Secretariat. The Group endorsed the proposed agenda.

The Terms of reference, agenda and list of participants are presented as Appendices 1, 2 and 3, respectively.

3. Evaluation of two applications from a Member for official recognition of zonal negligible BSE risk status

United Kingdom (UK)

In August 2024, the UK submitted a dossier seeking recognition of negligible BSE risk status for two separate zones:

- One zone consisting of England and Wales. This zone was recognised as a zone having a controlled BSE risk status since May 2017.
- One zone consisting of Scotland. This zone was recognised as a zone having a controlled BSE risk status since December 2018.

All information provided and reported in this report relates to the past eight years (2016-2023), so the conclusions of this report can only refer to that period. Given the information provided in the dossier, the two zones were assessed simultaneously. The Group requested additional information and received clarifications from the UK during the evaluation of the dossier.

In accordance with the established procedures, the UK expert who participated in the meeting withdrew during the Group's assessment of the UK's dossier.

a) <u>Section 1: BSE risk assessment (Article 11.4.4. point 1)</u>

1. *<u>Entry assessment (Article 11.4.3. point 1a): assessment of the likelihood that the classical BSE agent has been introduced into the zones through the importation of commodities</u>*

   - Bovines

     The Group noted that all imported live bovines had come from countries posing either a controlled or a negligible BSE risk and import requirements were consistent with Chapter 11.4.

- Ruminant-derived protein meal

  The Group noted that, in the UK, animal by-products (ABPs) were divided into the following three categories based on the risk they pose to public and animal health, according to Regulation (EC) No 1069/2009, in decreasing risk:

  - Category 1: among which are the carcasses of ruminants, and commodities with the greatest BSE infectivity.
  - Category 2: including infectious animals, carcasses containing treatment residues or from dead livestock, animals culled for disease control purposes, manure, and digestive tract content.
  - Category 3: including slaughterhouse products which are fit, but not intended, for human consumption.

  The Group noted that imports of ruminant-derived protein meal derived from Category 1 ABP were strictly controlled by the Competent Authority (CA). Such products had only been imported from a country with a negligible BSE risk status, for use as fuel for combustion, after being processed in accordance with Article 11.4.19. Imports of Category 2 and 3 commodities had occurred from countries posing an undetermined BSE risk that had been assessed and approved by the CA. The Group concluded that even when these were imported for specific permitted uses including organic fertilisers, soil improvers, and pet food, and were not allowed to be used as ingredients for feed for farmed animals, their importation was not compliant with Article 11.4.13.

- Feed that contains ruminant-derived protein meal

  The UK reported that livestock feedstuffs containing meat and bone meal (MBM), protein meal or processed animal proteins (PAP) were not imported into either of the two zones.

- Fertilisers that contain ruminant-derived protein meal

  The Group noted that imports of fertilisers that contained ruminant-derived protein meal were in accordance with the *Terrestrial Code* (i.e. only imported from countries with a negligible BSE risk status and without commodities listed in Article 11.4.15.).

- Any other commodity that either is or could be contaminated by commodities listed in Article 11.4.15. (commodities with the greatest BSE infectivity)

  The UK described the conditions for the import of commodities listed in Articles 11.4.12. to 11.4.18 (e.g. blood, blood products, tallow with more than 0.15% impurities, tallow derivatives, dicalcium phosphate). The Group concluded that the import requirements for these commodities sufficiently reduced the likelihood of introduction of the classical BSE agent.

Conclusion of the entry assessment

Considering that ruminant-derived protein meal had been imported into the UK during the past eight years without fully complying with the relevant provisions of the *Terrestrial Code*, the Group concluded that the likelihood of the classical BSE agent entering the two UK zones during the period assessed was not negligible. Therefore, the Group recommended that the UK harmonise the requirements for importations of bovine commodities with the recommendations of Chapter 11.4. of the *Terrestrial Code* adopted in May 2023.

2. *Exposure assessment (Article 11.4.3. point 1b): assessment of the likelihood of bovines being exposed to the classical BSE agent either through imported commodities or as a result of the presence of classical BSE within the bovine population of the zones*

   a. *Livestock industry practices*

      i. *Demographics of the bovine population and production and farming systems*

         The UK explained that across both beef and dairy-farmed livestock, there were three different general production systems: indoor (intensive), outdoor (extensive) and semi-intensive. The Group noted that the UK had a compulsory individual cattle identification system whereby each bovine must have a passport. All movements must be reported and registered in the central database, allowing accurate and timely knowledge of the demographics of the bovine population. Any bovine’s death must be notified to the CA within seven days. The Group noted the presence of an inspection programme whereby sanctions were applied when breaches were identified. Documentary evidence of those was presented. The Group agreed that the information provided by the UK demonstrated good knowledge of the demographics of the bovine population and the production and farming systems.

ii. Feeding practices

The Group noted that, although there were different production systems, bovines were fed with mainly mixed rations, silage, grass, and hay. The Group also noted that concentrates of compounded feed was widely used by farmers in the UK.

iii. Slaughtering and waste management practices

The Group noted that the vast majority of bovines in the UK were slaughtered at slaughterhouses approved and monitored by the CA. The Group acknowledged that an official veterinarian ensured that all necessary precautions were taken to avoid contamination of meat with commodities with the greatest BSE infectivity or those considered unfit for human consumption during slaughter (including stunning), processing and removal. It was reported that daily and weekly operational checks, were audited by an independent body.

The Group noted that, although the number of bovines slaughtered on farms was not recorded centrally, it was estimated to be very low. On-farm slaughter was authorised in specific instances, as follows:

- for emergency slaughter, requiring antemortem inspection of the animal by a veterinarian, slaughter by a qualified person and movement of the carcass to an approved slaughterhouse for further processing;
- for private consumption by the owner. The bovine must be slaughtered by the owner or a person with a license delivered by the CA under the responsibility and supervision of the owner. The Group noted that in this case, no veterinary oversight was required and that the owner was responsible for organising the transport of any ABPs to an approved disposal facility, and all bovines aged 30 months and over must be sampled and tested for BSE.

The Group was also informed that, in all instances, the collection and disposal of fallen stock was audited by the CA to ensure compliance with the ABP regulations stipulating that fallen stock must be collected, identified and transported without undue delay to an approved disposal facility but a derogation existed for burial or incineration of cattle on certain remote islands of both zones, under the authorisation of the CA. The UK informed that BSE testing was mandatory for all fallen stock aged over 48 months.

Finally, materials unfit for human consumption were classified as Category 1, 2 or 3 ABPs as described above and managed as described in section 2.b.iv. of this report.

iv. Rendering practices

The UK reported that there were 16 rendering sites in England (eight in Scotland), three of which handle Category 1 ABP (two in Scotland) and approximately 40 on-farm incinerators.

The Group acknowledged the detailed explanations on the seven different rendering methods. Method 1 is aligned with point 1) of Article 11.4.19., while other methods are aligned with point 2) of the same article. However, if any of the other methods were used on Category 1 material, the resulting product must be incinerated. A breakdown of the number of rendering facilities operating, indicating type and source of material handled, species of origin, processing method and potential end use, among other details was provided for the preceding eight years. The Group noted that all rendering plants had to have processing methods, SOPs, and HACCP plans approved by the CA. The Group took note of a table summarising the inspections and number of infractions, over the past eight years and agreed that audits were conducted at a satisfactory frequency. The Group also noted that, while transporting raw ABPs, the containers/trailers/vehicles must be labelled with the category of ABP being transported.

The Group noted that products derived from rendering processes were subjected to strict legislative controls, relating to the risk category of the ABP and the species of the source material. The data provided showed that Category 1 ABPs were used mainly for biodiesel, followed by combustion and incineration. Finally, the Group noted that there were rendering plants that handled ruminant material and material from other species in the same facilities and some that handled mixed species, including ruminant Category 1 ABPs, but in all these instances, the end product was incinerated or rendered into tallow for later use as biofuel.

v. Feed production, labelling, distribution and storage

The Group noted that all feed businesses must be registered or approved by the CA and that regulations and controls on feed safety, traceability and operating standards of feed businesses existed throughout the feed chain. The UK explained that the only feed in which rendered ruminant products could be used as ingredients is pet food. Pet food containing rendered ruminant products are produced in dedicated pet food plants, which are approved by the CA. The only permitted animal proteins in ruminant feed are milk and milk-based products and colostrum, eggs and egg products, collagen and gelatine derived from non-ruminants and hydrolysed proteins derived from non-ruminants or from ruminant hides and skin.

Conclusion of livestock industry practices

The Group concluded that the livestock industry practices described above in the two zones under evaluation could have been conducive to recycling of the classical BSE agent, and therefore the implementation of BSE-specific risk mitigation measures needed to be assessed.

b. *An evaluation of BSE-specific risk mitigation measures (Article 11.4.3. point 1.b.ii.)*

i. *The nature and scope of the feed ban*

Feeding ruminant proteins to ruminants was prohibited in the UK in 1988. In August 1996, this was extended to ban the feeding of mammalian protein meal to all farmed animals and, in 2001, the reinforcement of the ban of feeding animal protein from both ruminants and non-ruminants to all farmed animals was introduced in the European Union (EU).

ii. *Commodities with the greatest BSE infectivity (as defined in point 1 of Article 11.4.15.)*

The Group acknowledged that the UK's definition of specific risk material (SRM) included all parts of the animal that were most likely to contain BSE infective material, if an animal were infected, and aligned with point 1 of Article 11.4.15. of the *Terrestrial Code.* The Group further noted that, in every slaughterhouse, a resident official veterinarian monitored and enforced the proper removal, collection, identification, separation, storage, staining (where appropriate), transport and disposal of commodities classified as Category 1 ABP. The Group was satisfied that, in addition, SRM and all body parts of dead animals cross-contaminated by SRM were considered Category 1 ABP and transported and destroyed using the same leak-proof transport and incineration process with or without prior rendering. The Group noted that rendered material from Category 1 ABP was only used for energy generation.

iii. *Parameters of the rendering process*

The Group was satisfied that the rendering parameters referred to in section 2.a.iv. of this report were aligned with Article 11.4.19.

iv. *Cross-contamination prevention*

The Group noted that Category 1 and 2 ABPs were stained with a blue colouring agent using a solution of such strength that the staining was clearly visible and remained visible after the SRM had been chilled or frozen. All Category 1 and 2 ABP processing products must be marked with glyceroltriheptanoate to distinguish them from the equivalent products of Category 3 ABPs. The Group further noted that rendering plants operated dedicated processing lines for different categories and species, and there were some generic mixed species rendering plants. The Group was informed that physical separation of different species and categories of ABPs was achieved with the use of dedicated trailers, containers (or full cleansing and decontamination between uses), reception areas, rendering equipment and end-product storage facilities for the different categories and species of ABPs. All operators who store ABPs must be approved to do so by the CA; it is a prerequisite for approval that operators handling more than one category of ABP must have conducted a risk assessment and put in place mitigation measures to prevent cross-contamination.

Pet food containing animal protein must not be kept in the same store on the farm as any livestock feed products, in feed production areas or in any area where farmed animals have access. All feed must indicate that the ingredient was produced on (or that the feedstuff contains ingredients which were produced on) premises where PAP (except fishmeal) is used in a manufacturing process, either by package labelling or via documentation accompanying the ingredient or feedstuff. The UK provided documentary evidence that infractions were reported and properly investigated.

v. *Awareness programme under the scope of the feed ban*

The Group agreed that all stakeholders along the food and feed chain were regularly provided with updates and information on BSE and the feed ban during the registration of the businesses, frequent controls and continuous professional education. Methods used were diverse and included in-person visits, communication via professional bodies and the CA's website.

vi. Monitoring and enforcement of the feed ban

The UK reported a risk-based control programme in place for all businesses throughout the feed chain to investigate any possible contamination of feed by prohibited material.

In terms of controls, the UK explained that the CA provided a regulatory framework which ensured that all manufacturers/users throughout the feed sector complied with the feed ban and carried out regular tests to ensure ruminant feed was not contaminated with protein meal at any stage of the feed chain, including during storage on premises that may use organic fertilisers and soil improvers containing ABP or PAP.

The Group noted that feed-producing establishments, including all feed mills, mobile feed mixers and on-farm mixers, were subject to regular inspection by the CA, which included sampling of feed ingredients and finished feed to check for the presence of mammalian proteins. Any positive findings were thoroughly investigated, and suspect feed was withheld from livestock until laboratory tests indicated that the feed was free from MBM or PAP. When the outcome of the investigation was inconclusive or positive, the feed was destroyed, and the feed plant was cleaned and disinfected before it could be used for further feed processing and storage. Onward tracing of any feed produced and sent to other premises, including farms, was also conducted and feed was restricted and destroyed.

The Group was satisfied by the programme coverage and frequency of the different inspections. Documentary evidence was provided on the reported number and type of non-compliances, as well as the results of the tests carried out in feed mills (provided for the last eight years) and the mitigation measures in place when contamination or a non-compliance were identified.

Conclusion of the evaluation of BSE-specific risk-mitigation measures

The Group concluded that the BSE-specific mitigation measures implemented in the two zones under evaluation were adequate to ensure a negligible likelihood of recycling the BSE agent within the bovine population.

3. *Consequence assessment (Article 11.4.3. point 1c)*

The Group did not perform a consequence assessment, as the conclusion of the exposure assessment is that the likelihood of bovines being exposed to the classical BSE agent either through imported commodities or as a result of the presence of classical BSE within the bovine population of the country during the preceding eight years is negligible.

4. *Risk estimation (Article 11.4.3. point 1d)*

Considering the conclusions from the entry and exposure assessments, the Group determined that the overall risk of the classical BSE agent being recycled within the bovine population was negligible during the preceding eight years.

b) Section 2: Surveillance (Article 11.4.4. point 2)

1. *Awareness and training programmes (Article 11.4.20. point 3a)*

The Group noted that an awareness programme on BSE had been present since 1988 and had been continuously applied over both zones and included all relevant stakeholders (veterinarians and relevant officials, cattle farmers, slaughterhouse operators, and personnel in the ABP sector). While the UK reported that these information campaigns were very frequent, no details on frequency or attendance were provided.

The Group also acknowledged that the UK had sufficient contingency and preparedness plans in place for BSE.

2. *BSE reporting system (Article 11.4.20. point 3b)*

The Group noted that BSE had been notifiable since 1988 as per legislation. The Group was informed that measures to stimulate notification, penalties for failure to notify BSE suspect cases, and a compensation policy for farmers regarding the animals taken (suspects and cohorts) was in place. The Group noted that there were criteria to raise suspicion, and decision trees and protocols were in place to identify and investigate clinical suspects. The UK also provided templates and forms aimed at monitoring and standardising all the steps from the notification of a suspicious case until the animal was either released or culled and tested for BSE. The Group concluded that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

3. *Laboratory testing (Article 11.4.20. point 3c)*

The UK informed that the National Reference Laboratory (NRL) for BSE in the UK was at the Animal Plant Health Agency (APHA, Weybridge), a WOAH Reference Laboratory for BSE and scrapie. The Group was informed that surveillance samples were screened by an APHA-designated laboratory using tests compliant with Chapter 3.4.5 of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*). Any inconclusive or positive samples were tested further at the NRL. The Group took note that the NRL provided annual proficiency testing to the APHA-designated laboratories for rapid screening tests and that the NRL participated annually in the annual European Union Reference Laboratory (EURL) External Quality Assurance (EQA) covering BSE Western Blot and Immunohistochemistry.

The Group concluded that the laboratory diagnosis for BSE conducted in the two zones of the UK was compliant with Chapter 3.4.5 of the *Terrestrial Manual*.

4. *Evaluation procedures and protocols to identify animals targeted for BSE surveillance, to determine animals to be subjected to laboratory testing, to collect and submit samples for laboratory testing, and to follow up BSE positive findings with epidemiological investigation (Article 11.4.20. point 3d)*

- Definition of the target population for BSE surveillance and determination of animals to be subjected to laboratory testing

  The Group took note of a list provided by the UK of common bovine disorders with clinical signs compatible with BSE and their prevalence. The Group noted that the UK still carried out surveillance as per the requirements of the *Terrestrial Code* (2022) while transitioning to the current requirements. Surveillance requirements were driven until 2021 by Regulation (EC) No 999/2001. After 2021, the EU requirements for surveillance were assimilated into national legislation. The UK informed that national legislation requires the testing of all fallen stock cattle, emergency slaughter cattle aged over 48 months regardless of clinical signs or history, and animals that failed antemortem inspections aged over 48 months. While not required by the current provisions of the *Terrestrial Code*, the UK allowed for offspring up to 24 months and cohorts from classical and atypical BSE cases to be culled and sampled for BSE testing if deemed necessary.

- Reporting of bovines described in points 2a to 2d of Article 11.4.20.

  The UK informed that:

  - all bovines displaying progressive clinical signs suggestive of BSE and those unable to walk or rise without assistance must be reported to the CA by keepers, veterinarians, operators at animal gatherings or veterinarians carrying out antemortem inspections at abattoirs;
  - all bovines that underwent an antemortem inspection at slaughter and showed behavioural or neurological signs must be reported to the CA;
  - all fallen stock over 48 months were sampled for BSE testing in Great Britain.

  The Group agreed that protocols for reporting investigation of clinical suspects with forms for each step of the reporting procedure were in place and that the age of animals investigated could be reliably assessed using the mandatory individual animal identification.

  The Group also noted that owners and keepers were not discouraged from reporting suspected cases of BSE, as animals classified as BSE suspects or as cohorts and offspring of a confirmed BSE case were compensated at 100% of market value, including disposal costs; additionally, failure to report was considered an offence.

  The Group concluded that the UK had a robust reporting system and that its surveillance system, while still not fully adapted to current requirements of the *Terrestrial Code*, targets the population where BSE is more likely to be detected, including bovines showing signs of the clinical spectrum of BSE.

- The collection and submission of samples for laboratory testing

  The Group noted that live BSE suspects (passive surveillance) were either:

  i. transported in a specialist APHA vehicle (covered and leak-proof) to the NRL for further clinical observation prior to euthanasia and sampling; or,

  ii. if not fit for transport, first euthanised on the farm and transported to a Veterinary Investigation Centre, where brainstem samples were collected by Veterinary Investigation Officers after a post-mortem examination and sent to the NRL for confirmatory testing.

The UK informed that bovines failing antemortem inspection at slaughter were reported similarly as live clinical suspects and, if suspicion was confirmed, sampled at the abattoir, as described below for bovines sampled as part of active surveillance.

The Group also noted that fallen stock must be collected, identified and transported without undue delay to an approved disposal facility, at the cost of the owner, by registered fallen stock transporters or ABP collection centres. Fallen stock aged over 48 months must be delivered to a disposal facility approved for BSE sampling.

Brainstem samples of fallen stock over 48 months (mandatory testing) or other bovines sampled as part of active surveillance are collected at Transmissible Spongiform Encephalopathy (TSE) Fallen Stock Sampling Sites or abattoirs, respectively, by trained samplers and shipped to the TSE rapid-testing laboratory by a designated courier company. If the BSE rapid test is positive, the sample will be sent to the NRL for confirmatory diagnosis.

The Group appreciated that all procedures –document and ear tag checks, DNA testing to reconcile animal and sample, and audits – ensured a full chain of evidence from sample collection to carcass disposal, with laboratories monitoring the sampling and form completion to verify accuracy and compliance.

- The follow-up epidemiological investigations for BSE-positive findings

  The Group commended the thorough epidemiological investigation carried out after cases of BSE and the UK's transparency in publishing the reports (*cf.* c) section 3 below).

- Summary of surveillance in the past eight years

  The Group took note of the tables summarising the number of bovines reported and tested as part of the BSE surveillance and commended the UK's efforts to align with the tables under Article 1.8.5.

5. *Animals subjected to laboratory testing*

   The Group noted that all bovines reported showing signs of the clinical spectrum of BSE were subjected to laboratory testing with negative results.

Conclusion of the evaluation of the surveillance programme

The Group concluded that robust surveillance was conducted in the two zones under evaluation and that notification and reporting systems were well supported by adequate legislation. Nevertheless, the Group recommended the UK to continue its efforts to adjust its surveillance to the current requirements of Article 11.4.20. of the *Terrestrial Code*.

c) Section 3: History of occurrence and management of cases of BSE and bovines affected by atypical BSE (Article 11.4.4. points 3 and 4)

The Group took note that there had been three cases of classical BSE between 2016 and 2024 (two in Scotland and one in England and Wales) and 16 cases of atypical BSE since 2004 (14 in England and Wales and two in Scotland). The Group took note that all cases had been removed from the food and feed chains and disposed of as Category 1 ABP. All cases of classical BSE were born after the reinforced feed ban (banning the feeding of mammalian protein to all farmed animals). The Group commended the thorough investigation of every case of classical BSE that was confirmed during the past eight years and noted that the investigations had not revealed a definitive source of infection.

In May 2024, Scotland reported the occurrence of an indigenous case of classical BSE in a bovine born in October 2016 (i.e. born after the starting date[1]). The Group took note of the conclusion of the Scientific Commission for Animal Diseases (the Scientific Commission) on Scotland's compliance with Articles 11.4.8. and 1.8.7. For this latest case, the Group agreed that Scotland: (a) timely submitted to WOAH the notification of the occurrence, (b) submitted a report within 90 days of the confirmation of the case demonstrating that all the risk factors identified in the risk assessment continued to be adequately managed as to maintain a negligible risk of recycling the BSE agents in the bovine population, and (c) disposed of the case in a way that ensured that it did not enter the feed and food chains. The Group noted that the epidemiological investigation concluded that the most likely source pathway was exposure to residual feed material remaining in a silo installed before the reinforced feed ban was implemented on 1 August 1996. The particular silo was decommissioned and removed. The Group commended the UK for the ongoing work to raise awareness among farmers and decommission all pre-1996 silos.

[1] 'Starting date' is defined as the year from which the risk of BSE agents being recycled within the cattle population could be considered as negligible.

d) ***Section 4: Determination of the date from which the risk of BSE agents being recycled within the bovine population has been negligible***

The Group concluded that, based on evidence provided for this evaluation, the year from which the risk of BSE agents being recycled within the bovine population has been negligible would be 2016 in both the zone of England and Wales and the zone of Scotland. However, the Group also noted that, due to the current and past BSE risk statuses of these zones, the starting date would remain as published on the WOAH website (i.e. 2008 for both the zone of England and Wales and the zone of Scotland).

e) ***Section 5: Compliance with the questionnaire in Chapter 1.8.***

The Group agreed that the dossier submitted was in accordance with Chapter 1.8. 'Application for official recognition by WOAH of risk status for BSE' of the *Terrestrial Code*.

Conclusion

Considering the information submitted in the dossier and the UK's answers to follow-up questions raised, the Group concluded that the applications were compliant with the requirements of Article 11.4.4., and Chapter 1.8. of the *Terrestrial Code*.

Determination of the BSE risk status

The Group therefore recommended that the zone of England and Wales and the zone of Scotland be recognised as zones of the UK having negligible BSE risk status.

Recommendations

The Group recommended that the UK (also detailed in the relevant sections above): i) continue its efforts to adjust its surveillance, and ii) harmonise the requirements for importations of bovine commodities according to the current Chapter 11.4. of the *Terrestrial Code* (adopted in May 2023).

4. Evaluation of the risk assessments of two Members already having an official negligible BSE risk status

At the Scientific Commission's request, the People's Republic of China (hereafter referred to as China) and India submitted updated BSE risk assessments following the provisions of the BSE standards adopted in May 2023. The Scientific Commission asked the Group to evaluate these assessments ahead of its February 2025 meeting.

All information provided, and reported in this report relates to the past eight years (2016-2023), so the conclusions of this report can only refer to that period.

People's Republic of China[2]

a) ***Section 1: BSE risk assessment (Article 11.4.4. point 1)***

1. *Entry assessment (Article 11.4.3. point 1a): assessment of the likelihood that the classical BSE agent has been introduced into the zone through the importation of commodities*

   The Group noted that China's risk of entry assessment was mostly based on the occurrence of BSE cases in exporting countries rather than the WOAH official BSE risk status held by the countries.

   - Bovines

     The Group noted that, between 2016 and 2023, China imported live cattle from countries with a negligible BSE risk status according to the provisions of Chapter 11.4. of the *Terrestrial Code*. In addition, 2,176 live bovines (0.12% of all cattle imported during the period assessed) were imported for direct slaughter from a single country posing an undetermined BSE risk. The Group noted that these animals were individually identified and fed with feed, which was produced in two facilities in the exporting country. These facilities produced feed only for ruminants and were visited and inspected by Chinese authorities to confirm that the feed contained no ingredients derived from artiodactyls. In addition, the animals were subject to a protocol agreement signed with the exporting country that required the country to enact, and effectively implement,

[2] A zone designated by the Delegate of China in a document addressed to the Director General in November 2013, consisting of the People's Republic of China with the exclusion of Hong Kong and Macau, recognised with a negligible BSE risk status since May 2014.

a national ban on feeding ruminants with animal-derived feed. Nevertheless, from the additional clarification provided, the Group noted that the imported animals had been born before the feed ban was effectively enforced by the exporting country. While the proportion of imported animals was very small, the Group considered that the likelihood of entry of classical BSE through live bovine imports was not negligible.

The Group further noted that live cattle imported from the country posing an undetermined BSE risk were subject to quarantine for BSE control purposes, among other diseases. Given the extended incubation period of BSE and the lack of pathognomonic clinical signs, the Group highlighted that, for the importation of bovine, quarantine is not an effective measure in preventing the introduction of BSE.

- Ruminant-derived protein meal

  The Group noted that limited quantities of ruminant-derived “greaves” had been imported into China from a country and a zone posing an undetermined BSE risk. While the Group acknowledged that these commodities were intended for human consumption or industrial purposes and were labelled as ‘not for ruminants’, the likelihood that the classical BSE agent had been introduced into the country via greaves was not negligible.

- Feed that contains ruminant-derived protein meal

  China reported that no feed containing ruminant-derived protein meal had been imported during the period assessed.

- Fertilisers that contain ruminant-derived protein meal

  China reported that fertilisers that contain ruminant-derived protein meal had not been imported during the period assessed.

- Any other commodity that either is or could be contaminated by commodities listed in Article 11.4.15. (commodities with greatest BSE infectivity)

  The Group noted that meat and meat products that included bone-in-beef, boneless beef and beef offal, as well as blood and blood products derived from bovines (except foetal blood), had been imported into China from multiple countries posing negligible, controlled and undetermined BSE risk. While the Group acknowledged that these products were intended for human consumption, the Group considered that the measures applied on the imports of these products were not sufficient to conclude the likelihood of the introduction of classical BSE agent as negligible.

  The Group further noted that bovine fat had been imported from countries posing an undetermined BSE risk mainly for chemical production and, to a lesser extent, for pig and poultry feed. In the additional information provided, China clarified that fat with more than 0.15% insoluble impurities in weight had never been imported.

  The Group acknowledged that importation of any commodities listed in points 1 and 2 of Article 11.4.15. and any other commodities contaminated by them was prohibited in China.

Conclusion of the entry assessment:

Considering that live bovines and ruminant-derived protein meal had been imported into China during the past eight years without fully complying with the relevant provisions of the *Terrestrial Code*, the Group concluded that the likelihood of the classical BSE agent entering China during the period assessed was not negligible. The Group recommended that China harmonise the requirements for importations of bovine commodities with the recommendations of Chapter 11.4. of the *Terrestrial Code* adopted in May 2023.

2. *Exposure assessment (Article 11.4.3. point 1b): assessment of the likelihood of bovines being exposed to the classical BSE agent either through imported commodities or as a result of the presence of classical BSE within the bovine population of the zone*

   a. *Livestock industry practices*

      i. *Demographics of the bovine population and production and farming systems*

      The Group noted that China’s cattle population was approximately 100 million, with the vast majority (~83%) destined for beef production. The Group took note of a steady increase in large and medium-scale farming enterprises with more intensive production in both the dairy and beef sectors and a decrease in small-scale farms. China informed that cattle were also kept extensively in the country, either as work animals or for dual work/beef purposes. China reported that all cattle were individually identified by a single tag and that ruminants were not mixed with other species, neither on intensive nor smallholder farms.

ii. *Feeding practices*

The Group noted that in intensive production systems, rations were formulated on-farm using roughage mixed with concentrates produced commercially or made in-house, specifically prohibiting ruminant-derived ingredients, except for milk or milk products. In non-intensive dairy farms, forages, corn, and soybean meal were used as primary cattle feed. In extensive beef production systems, cattle grazed on natural vegetation and plant-based supplements were used in winter (silage, hay, grain and soybean meal).

iii. *Slaughtering and waste management practices*

The Group noted that the majority of cattle were slaughtered at slaughterhouses certified by the Department of Agriculture and Rural Affairs for slaughtering, selling or transporting livestock and their products, with 26 to 30 million cattle processed annually. The Group further noted that veterinary inspectors were assigned to these establishments and were responsible for immediately notifying the CA of the presence or suspicion of diseases, including BSE. China described ages at slaughter of cattle according to their purpose and farming system: 4.5 to 5 years old in intensive dairy systems and 1.5 to 2 years for beef cattle. In the additional information provided, China confirmed that commodities with the greatest BSE infectivity listed in point 1 of Article 11.4.15. were not removed from slaughtered animals but used for human consumption.

The Group further noted that home slaughtering was allowed in China and mainly practised in rural areas for personal consumption. The Group acknowledged that these animals were well-documented and did not enter the market.

The Group further noted that the disposal of fallen stock, condemned animals and animal products that failed inspection, was carried out by incineration, rendering, high temperature, deep burial or chemical treatment. According to the protocol described by China, cattle confirmed or suspected of being infected with BSE were incinerated at >850°C Upon request, China confirmed that healthy animals tested for BSE (active surveillance) were destined for human consumption.

iv. *Rendering practices*

The Group noted that there were more than 740 rendering plants certified by the Department of Agriculture and Rural Affairs in China and that they all operated as biosafety disposal premises handling only sick or dead animals, mainly pigs and poultry and rarely bovines and sheep. The Group further noted that materials for rendering were rarely separated or organised based on their species when being stored or handled. China informed that rendered products were only used for biodiesel, industrial purposes or organic fertilisers for fruit trees and flowers with high value, not in land where bovines graze or bovine feed was harvested.

China reported that no rendering plants were handling healthy animals, as healthy slaughtered animals, which contained commodities with the greatest BSE infectivity, were used for human consumption or in animal feed for non-ruminant species.

The Group acknowledged that national and provincial organisations regularly offered technical guidance on biosafety disposal practices to help facilities improve operations, technology, and waste resource utilisation. Awareness was raised through interpreting regulations, developing educational materials on biosafety disposal policies and sharing successful case studies to support local animal health supervision institutions.

v. *Feed production, labelling, distribution and storage*

The Group noted that feed mills producing ruminant feed had to be licensed and approved by the provincial or local feed administration department before starting production. Animal-derived rendered products were not used as ingredients in feed as they were derived from sick and dead animals. However, animal products derived from healthy ruminants were used for producing feed for non-ruminants. The Group noted that feed for ruminants and non-ruminants was produced in the same facilities.

China reported that, as of 2024, there were 3,429 licensed manufacturers producing additive premixes, with 53% of them allowed to make ruminant premixes. Among them, 2% produced only ruminant premixes. Additionally, there were 7,380 manufacturers producing compound, concentrated, or concentrate supplement feeds, with 25% of them qualified to produce ruminant feed and 7% among them producing only ruminant feed.

From the additional information provided, the Group took note of a mandatory national standard named ‘Feed Labelling’, according to which animal-derived products should be labelled with the name of the species included and if the animal-derived feed contains sources of animal proteins other than milk or milk products it should be marked as ‘not for ruminants’. The Group further noted that storage and transport of feed was regulated by an Order of the Ministry of Agriculture that required facilities manufacturing feed for multiple species including ruminants, to store feed of different types separately. According to the same legislation, vehicles transporting ruminant feed did not mix different types of feed.

Conclusion of livestock industry practices

Considering the use of ruminant-derived products in the production of feed for non-ruminants and the presence of feed mills producing both feed for ruminants and non-ruminants in the same facility, the Group concluded that the industry practices in China could have been conducive to the recycling of the classical BSE agent. Therefore, the evaluation of mitigation measures for the risks identified was necessary.

b. An evaluation of BSE-specific risk mitigation measures (Article 11.4.3. point 1.b.ii.)

i. The nature and scope of the feed ban

The Group noted that China’s legislation enforced since 2012 prohibited the use of animal-derived product (except milk or milk products) in ruminant feed.

ii. Commodities with the greatest BSE infectivity (as defined in point 1 of Article 11.4.15.)

The Group noted that there were no specific requirements in China for the management (and removal at slaughter) of commodities with the greatest BSE infectivity listed in point 1 of Article 11.4.15., as such commodities derived from healthy animals were mainly used for human consumption, due to cultural preferences, or for feed for non-ruminants. In instances of sick or dead animals, the entire animal was disposed of at rendering plants (*cf.* sections 2. a) iii) and iv) above).

iii. Parameters of the rendering process

From the additional information provided by China, the Group noted that, while the temperature and pressure parameters were in accordance with the provisions of Article 11.4.19., the size of the particles of the rendered products was not aligned with these requirements. However, the Group acknowledged that all rendered products were only used for biodiesel, industrial purposes or organic fertilisers (which are not used in land where bovines graze or where bovine feed was harvested) and not in the production of feed of any animal species (*cf.* section 2. a) iv) above).

iv. Cross-contamination prevention

While there were feed mills in China producing both feeds for ruminants and non-ruminants, the Group noted that ruminant feed and feed containing animal-derived ingredients were manufactured on separate production lines as per legislation enforced since 2012.

v. Awareness programme under the scope of the feed ban

The Group took note of a top-down cascade training programme in place with the National Animal Husbandry Services organising annual training on topics such as relevant legislation, licensing requirements and labelling standards for feed-related authorities’ staff at the provincial level who then train agricultural authorities’ staff at the county level. The latter then train employees of entities engaging in animal and feed production (including storage, sale and distribution) under their authority.

In addition, the Group noted that China had been running an awareness programme on BSE since 2016 for local veterinarians by distributing brochures and delivering on-site lectures, with subsequent assessment of the trainees to ensure the programme’s effectiveness.

vi. Monitoring and enforcement of the feed ban

The Group noted that monetary penalties and criminal charges were foreseen in instances of breaching the feed ban.

The Group took note of a regulation that required manufacturers of feed and feed additives to check or test all outsourced feed ingredients according to regulatory standards. Since 2003, China has established the annual ‘Routine Monitoring Plan for Ingredients of Bovine and Sheep Origin Contained in Ruminant Feed’ to inspect and monitor these ingredients in ruminant feed. The Ministry of Agriculture and Rural Affairs (MARA) conducts annual on-site inspections of feed manufacturers, focusing on preventing ruminant feed contamination by ruminant products, production line and warehouse inspections, and transportation records. Local feed administration departments also routinely inspected manufacturers and had the authority to cancel ruminant feed production licenses if exclusive production lines were absent, and to penalise violations involving the addition of unauthorised animal-derived ingredients. The China Feed Industry Association (CFIA) guides, sets standards, and audits feed production while promoting compliance with regulations.

The Group further noted that MARA sampled more than 15,000 batches of feed every year to monitor for bovine and ovine-derived ingredients and potential cross-contaminants using a real-time fluorescent PCR. Feed samples were taken both at feed mills and on farms/premises where feed is compounded on-site.

The Group noted that no infractions had been detected during the aforementioned inspections and on testing in the period assessed. The Group requested that when reconfirming its BSE risk status in November 2025, China provide a description of the elements being checked during these inspections and clarify whether the negative data encompasses only BSE-related non-compliances or any type of infractions.

Conclusion of the evaluation of BSE-specific risk mitigation measures

The Group concluded that China's BSE-specific mitigation measures were adequate to ensure a negligible likelihood of recycling the BSE agent within the bovine population.

3. *Consequence assessment (Article 11.4.3. point 1c)*

   The Group did not perform a consequence assessment, as the conclusion of the exposure assessment is that the likelihood of bovines being exposed to the classical BSE agent either through imported commodities or as a result of the presence of classical BSE within the bovine population of the country during the preceding eight years is negligible.

4. *Risk estimation (Article 11.4.3. point 1d)*

   Considering the conclusions from the entry and exposure assessments, the Group determined that the overall risk of the classical BSE agent being recycled within the bovine population was negligible during the preceding eight years.

b) Section 5: Compliance with the questionnaire in Article 1.8.4.

The Group noted that China had not strictly followed the format laid out in Article 1.8.4. of the *Terrestrial Code*. The Group recommended that, for future revisions of its risk assessment, China follow the provisions of the 'Application for official recognition by WOAH of risk status for bovine spongiform encephalopathy' (Chapter 1.8.) which enables Members to evaluate the risk of the classical BSE agent being recycled within the bovine population by identifying all potential factors associated with the occurrence of BSE and their historic perspective.

Whilst China had provided some information on the BSE surveillance conducted in the country, the Group did not assess this part as it was not mandated to do so by the Scientific Commission. BSE surveillance data and information of Members having official BSE risk status recognised by WOAH will be assessed through the annual reconfirmation procedure.

Conclusion

Considering the information submitted in the dossier and the answers received to the additional questions raised, the Group concluded that China’s risk assessment was compliant with the requirements of Article 11.4.4 point 1 of the *Terrestrial Code* (2024). Therefore, the Group recommended that China’s negligible BSE risk status be maintained.

Recommendations to China:

The Group recommended that China (also detailed in the relevant sections above):

- For importation of bovines, quarantine should not be considered as an effective measure to prevent the introduction of BSE into the country, given the extended incubation period of BSE.

- harmonise the requirements for importations of bovine commodities according to the current Chapter 11.4. of the *Terrestrial Code* (adopted in May 2023). To this end, the risk assessment for entry of the classical BSE agent should be based on the BSE risk status of the exporting countries as recognised by WOAH rather than on the historical occurrence of BSE cases.
- provide a description of the elements being checked during feed mill and rendering plant inspections and clarify whether the absence of infractions refers only to BSE-related non-compliances or have there been no infractions at all, of any type.

The Group recommended that the aforementioned information be submitted to WOAH when China reconfirms its BSE risk status.

In addition, the Group recommended that China conduct any future BSE risk assessment in accordance with the provisions of Chapter 1.8. 'Application for official recognition by WOAH of risk status for bovine spongiform encephalopathy'.

India

India has a negligible BSE risk status officially recognised by WOAH since May 2010.

a) <u>Section 1: BSE risk assessment (Article 11.4.4. point 1)</u>

1. *<u>Entry assessment (Article 11.4.3. point 1a): assessment of the likelihood that the classical BSE agent has been introduced into the country through the importation of commodities</u>*

   - Bovines

     India imported live bovines from only three countries, all with negligible BSE risk status and exclusively for breeding purposes. Based on the description of the import requirements and health certifications provided by India, the Group considered that the likelihood of entry of classical BSE through live bovine imports was negligible.

   - Ruminant-derived protein meal

     India reported that imports of ruminant-derived protein meal were prohibited during the period assessed.

   - Feed that contains ruminant-derived protein meal

     India reported that imports of feed containing ruminant-derived protein meal, other than pet food, were prohibited during the period assessed.

   - Fertilisers that contain ruminant-derived protein meal

     India imported organic fertilisers that contained ruminant-derived protein meal from countries posing controlled and undetermined BSE risk without explicit assurance that these were not made from commodities with the greatest BSE infectivity. The Group acknowledged that the risk of exposure was sufficiently mitigated, as the fertiliser or its products or residues were prevented from directly or indirectly entering the animal feed chain. Nonetheless, for the purposes of the entry assessment, the Group concluded that the likelihood of entry of classical BSE through imports of these fertilisers was not negligible for the period assessed.

   - Any other commodity that either is or could be contaminated by commodities listed in Article 11.4.15. (commodities with greatest BSE infectivity):

     The Group noted that the import of tallow was prohibited in India during the period assessed and that import requirements for blood and blood products were appropriate. Information on import requirements for dicalcium phosphate with traces of protein or fat was not provided despite being requested. Therefore, the Group could not reach a conclusion on the likelihood of entry of classical BSE through imports of these commodities for the entire period assessed.

Conclusion of the entry assessment

Considering that the risk associated with certain commodities, such as dicalcium phosphate, remained unclear and that fertilisers had been imported from countries posing an undetermined BSE risk during the period assessed without fully complying with the relevant provisions of the *Terrestrial Code*, the Group concluded that the likelihood of the classical BSE agent entering India during the period assessed could not be considered negligible. The Group recommended that India harmonise the requirements for importations of bovine commodities with the recommendations of Chapter 11.4. of the *Terrestrial Code* adopted in May 2023.

2. ***Exposure assessment (Article 11.4.3. point 1b): assessment of the likelihood of bovines being exposed to the classical BSE agent either through imported commodities or as a result of the presence of classical BSE within the bovine population of the country***

a. *Livestock industry practices*

i. *Demographics of the bovine population and production and farming systems*

India informed that it had a cattle population of approximately 193 million, with most cattle raised on small holdings with fewer than five animals. In addition, India described that farmers typically owned a few cattle, buffalo, sheep, and goats, while keeping or farming of pigs, horses, and camels were much less common. India reported that ruminants were not mixed on farm with other species.

ii. *Feeding practices*

The Group noted that in India, cattle primarily ate cultivated green fodder, crop residues, homemade concentrate mixtures or compound cattle feed. However, given the size of the small-scale system, compounded feed was used infrequently. India also mentioned that it was rare to rear poultry and bovines on the same premises and non-ruminant feed containing ruminant products was of higher cost than cattle feed, so was unlikely to be fed to ruminants.

iii. *Slaughtering and waste management practices*

The Group took note that cattle slaughter was rare in India for cultural reasons. India explained that as a result, export of cattle beef was prohibited and many bovines at the end of their productive lives were taken to shelters or left free to roam. India informed that fallen stock that died from infectious diseases were buried, while those that died from accidents or non-infectious causes were rendered at plants officially recognised by the CA.

India further explained that, although cattle slaughter was rare and on-farm slaughter was not practised, when cattle were slaughtered, it was performed in approved and registered slaughterhouses. India confirmed that commodities with the greatest BSE infectivity (as defined in point 1. of Article 11.4.15.) were removed from all slaughtered cattle and combined with other inedible products for rendering or for burial and that animals condemned as unfit for human consumption were either incinerated, chemically treated, or buried.

The Group noted that bovines suspected of BSE were euthanised, and brain samples were collected for testing at an approved laboratory. The carcasses, tissues, and offal were then buried or incinerated under supervision of the CA. Ashes were deep buried after being mixed with agricultural lime. Identification was confirmed through ear tags, tail tags, brands and tattoos.

iv. *Rendering practices*

India informed that rendering plants in “modern abattoirs” processed raw material from slaughtered buffalo and sheep only and that rendering of non-ruminant products was completed at dedicated facilities at chicken abattoirs. The Group noted that healthy slaughtered cattle could only be rendered at carcass utilisation centres, which were approved and supervised by veterinary authorities. It was further stated that these facilities handled multiple species (including ruminants) and that there were no separate facilities processing only ruminant material. India explained that material from mixed species, including ruminants, was processed for tallow if the carcass had adequate fat or else the material was buried or burnt with adequate care to prevent environmental contamination.

India further explained that the rendered products were either tallow used for soap, greaves used for fertiliser or bones used for bone meal in bone-crushing units to be used as fertilisers. India reported that due to socio-cultural and economic changes, these practices had largely declined and, as a result, carcasses were now mostly buried or burnt rather than processed.

Finally, the Group acknowledged that regular audits by state government-designated veterinarians and the Agricultural and Processed Food Products Export Development Authority (APEDA) ensured ongoing compliance with safety regulations. The Group noted that all rendering plants processing ruminant material had been visually inspected each year from 2016 to 2023.

v. *Feed production, labelling, distribution and storage*

The Group noted that about 90% of commercial cattle feed was mixed at feed plants and 10% on farms. Feed mills producing feed for dairy cattle were not under veterinary oversight but required a registration license by the Bureau of Indian Standards to operate.

India explained that ruminant-derived protein meal and tallow from ruminants (from “modern abattoirs”, i.e. those processing buffalo) were used in poultry feed and for industrial purposes. India informed that the operation of rendering plants was supervised by local veterinarians, who certified that each batch of meat-and-bone meal and greaves was used only for poultry feed.

The Group was informed that manufacturing units for poultry feed, cattle feed, and feed for other species were separate and ruminant proteins were never used in any of the feed mills for cattle.

Conclusion of livestock industry practices

The Group concluded that the livestock industry practices described above could have been conducive to recycling of the classical BSE agent, and therefore implementation of BSE-specific risk mitigation measures needed to be assessed.

b. *An evaluation of BSE-specific risk mitigation measures (Article 11.4.3. point 1.b.ii.)*

i. *The nature and scope of the feed ban*

The Group took note that the feed ban prohibiting the use of MBM in cattle feed was first introduced on 21 September 1998. In August 2001, this feed ban was extended to include all animal-origin products in ruminant feeds, except milk and milk products. Ruminant-derived protein meal and tallow may be used in poultry feed. In addition, India provided a signed memorandum from 2019 indicating that fertilisers, including ruminant-derived protein meal commodities, “should not find a way into the animal food chain directly or indirectly”.

ii. *Commodities with the greatest BSE infectivity (as defined in point 1 of Article 11.4.15.)*

The Group acknowledged that commodities with the greatest BSE infectivity were removed from slaughtered cattle and combined with other inedible products for rendering, incineration or burial.

iii. *Parameters of the rendering process*

The Group noted that rendering parameters were aligned with *Terrestrial Code* requirements.

iv. *Cross-contamination prevention*

The Group was informed that manufacturing units for poultry feed, cattle feed, and feed for other species were separate and that all feed mills for manufacturing cattle feed did not use ruminant proteins in their feed. Upon request, India clarified that there were no feed mills producing feed for both ruminants and other species.

v. *Awareness programme under the scope of the feed ban*

Further to additional requests, the Group was informed that all stakeholders were regularly made aware of the feed ban. However, no information was provided on the frequency of training sessions or attendance.

vi. *Monitoring and enforcement of the feed ban*

India provided evidence that all feed mills were inspected yearly over the period assessed, and samples were collected and tested for contamination with ruminant-derived proteins using ELISA or PCR methods. The Group took note that India had started using PCR only since 2023, as recommended by the Scientific Commission, but understood that the use of ELISA had not been completely abandoned.

Conclusion of the evaluation of BSE-specific risk-mitigation measures

The Group concluded that India's BSE-specific mitigation measures were adequate to ensure a negligible likelihood of recycling the BSE agent within the bovine population.

3. *Consequence assessment Article 11.4.3. point 1)*

   The Group did not perform a consequence assessment, as the conclusion of the exposure assessment is that the likelihood of bovines being exposed to the classical BSE agent either through imported commodities or as a result of the presence of classical BSE within the bovine population of the country during the preceding eight years is negligible.

4. *Risk estimation (Article 11.4.3. point 1d)*

   Considering the conclusions from the entry and exposure assessments, the Group determined that the overall risk of the classical BSE agent being recycled within the bovine population was negligible during the preceding eight years.

b) Section 5: Compliance with the questionnaire in Article 1.8.4.

The Group agreed that the dossier submitted was compliant with the format laid out in Article 1.8.4. of the *Terrestrial Code*. Whilst India had provided some information on the BSE surveillance conducted in the country, the Group did not assess this part as it was not mandated to do so by the Scientific Commission. BSE surveillance data and information of Members having official BSE risk status recognised by WOAH will be assessed through the annual reconfirmation procedure.

Conclusion

Considering the information submitted in the dossier and the answers received to the additional questions raised, the Group concluded that India's risk assessment was compliant with the requirements of Article 11.4.4 point 1 of the *Terrestrial Code* (2024). Therefore, the Group recommended that India's negligible BSE risk status be maintained.

Recommendations to India:

The Group recommended that India (also detailed in the relevant sections above):

- ensure that PCR was the only method used for testing feed for cross-contamination consistently throughout the country.
- harmonise the requirements for importations of bovine commodities according to the current Chapter 11.4. of the *Terrestrial Code* (adopted in May 2023).

The Group recommended that the aforementioned information be submitted to WOAH when India reconfirms its BSE risk status.

5. Review of the meeting and working procedure (summary tables)

The Group appreciated the revised working procedure with summary tables produced by the Status department to facilitate the Group's revision of submitted dossiers and reporting of its assessment. The Group revised this procedure and suggested some improvements. The Group requested the Scientific Commission and WOAH to provide guidance on whether the Group should evaluate applications from Members against standards on importations in effect at the time of the assessment or at the time of the relevant imports. This is particularly challenging for BSE, where the period assessed for countries applying for a negligible risk status is eight years.

6. Annual reconfirmation forms: supportive documented evidence and internal screening guidance for maintenance of official BSE risk status

In view of the new BSE annual reconfirmation form (according to the revised BSE standards adopted in May 2023) that will be used for the first time during the 2024 annual reconfirmation campaign, the Group provided its opinion on the information that Members would be expected to provide to maintain their official BSE risk status and how this should be assessed by WOAH. In this regard, the Group suggested the following:

- With regard to Question 2 a) of the form, Members selected for comprehensive review each year should provide an updated description of the industry practices regardless of whether their answer to this question is yes or no. This description will serve as a baseline for the following years, where Members will only describe relevant changes in practices.
- With regard to Question 4 a), Table 1, Members should report the intended use of:
  - imports of ruminant-derived protein meal, or any commodities containing such product from a country, zone or compartment posing a controlled or undetermined BSE risk;

- imports of commodities with the greatest BSE infectivity, as described in Article11.4.15., from a country, zone or compartment posing an undetermined BSE risk.

- With regard to Question 4 b), if Members have not updated their import requirements for bovine commodities to align with the provisions adopted in May 2023, they should explain how the measures already in place comply with the revised requirements. If alternative import requirements are implemented, Members should describe how they effectively mitigate the risk of entry of the classical BSE agent, demonstrating equivalency to the new standards.
- With regard to Question 5 a), Members should describe the actions taken to adapt their BSE surveillance to the current BSE standards.
- The Group highlighted that, according to Article 11.4.20 point 2, bovines that lie on the clinical spectrum of BSE should be targeted for BSE surveillance, and these animals should be reported and followed up with appropriate laboratory testing to accurately confirm or rule out BSE (atypical or classical). Therefore, with regard to Question 5 a), Table 2 on 'Record surveillance conducted in the past 12 months' of the form, the number of bovines tested for BSE should be identical to the number of bovines with clinical signs suggestive of BSE that were reported and evaluated by the Veterinary Services. Otherwise, the Member should provide an explanation.

The Group also proposed to split Table 1 on 'Record of imports in the past 12 months' per commodity to improve the user-friendliness of the form and to facilitate Members' reporting, in a harmonised manner from one year to the next.

7. Any other business

The Group recommended that WOAH sensitise Members further on the revised BSE standards and organise training to raise awareness on the key changes made in the *Terrestrial Code* and the annual reconfirmation form, and on how Members should conduct and annually update their risk assessment based on Chapters 11.4. and 1.8.

8. Adoption of the report

The Group reviewed the draft report and agreed to circulate it electronically for comments before the final adoption. Upon circulation, the Group agreed that the report adequately captured the discussions.

…/Appendices

Appendix 1 Terms of reference

***AD HOC* GROUP ON THE EVALUATION**

OF BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) RISK STATUS OF MEMBERS

1-4 October 2024

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Purpose

The purpose of the *ad hoc* Group on the evaluation of bovine spongiform encephalopathy (BSE) risk status of Members (the Group) is to evaluate applications for official recognition of BSE risk status of Members.

Background

In accordance with the procedure for official recognition of animal health status, Members can be officially recognised by WOAH as having a negligible or controlled BSE risk status through the adoption of a resolution by the World Assembly of Delegates (the Assembly) in May every year. A Member wishing to apply for the official recognition of its BSE risk status by WOAH should complete and submit the relevant questionnaire laid out in Chapter 1.8. of the *Terrestrial Animal Health Code* (*Terrestrial Code*) and comply with all requirements specified in the *Terrestrial Code*. The Scientific Commission for Animal Diseases (Scientific Commission) is responsible for undertaking, on behalf of the Assembly, the assessment of Members' applications for their compliance with WOAH standards. The assessment carried out by the Scientific Commission is based on the recommendations formulated by a relevant *ad hoc* Group. *Ad hoc* groups are convened under the authority of and report to the Director General.

Specific issues to be addressed

The Group will evaluate Members' applications in detail on their compliance with the requirements specified in the *Terrestrial Code* for BSE. Based on the evaluations, the Group will provide its conclusions and recommendations to the Scientific Commission.

Prerequisites

The Group members should:

- Sign the Undertaking on Confidentiality of information (if not done already);
- Complete the Declaration of Interest Form;
- Understand that the membership of the Group may be retained between its meetings to ensure continuity of the work.

Actions to deliver

Before the meeting

Upon reception of an application from a Member, the Status Department (SD) conducts a preliminary screening to check the conformity of the dossier (structure of the dossier in accordance with the SOP and with the questionnaire under Chapter 1.8. of the *Terrestrial Code*, main sections of the questionnaire, regular notification to WOAH, payment of the fee, Performance of Veterinary Services (PVS) report, etc.). If an information gap is identified, the SD requests additional information from the Member.

As the PVS reports are bound by the rules on confidentiality of information of the WOAH, the SD and experts will consider for the evaluation the available PVS report(s) if not obsolete (PVS reports from more than five years ago) or confidential.

The SD will send the working documents to the Group, including the dossiers received from applicant Members, at least one month before the Group meeting (i.e. **2 September 2024**).

The experts can request support from the SD at any time.

The SD suggests the nomination of a Chair and Rapporteur for the Group's consideration.

The SD can suggest a preparatory meeting with the Chair, the Rapporteur or all experts to address specific points in advance, if needed.

The experts are expected to:

- Be familiar with Chapters 1.8. and 11.4. of the *Terrestrial Code*;

- Evaluate and study in detail all dossiers provided by WOAH;
- Take into account any other information available in the public domain that is considered pertinent for the evaluation of the dossiers;
- Summarise the dossiers according to the *Terrestrial Code* requirements by completing the summary tables provided by the SD (the summary tables will be provided at a later stage along with the working documents for the meeting). Experts are expected to capture and summarise in each corresponding section of the summary table the main gaps as well as strengths identified during the assessment of the dossiers, using extracted texts or reference to pages/annexes from the application;
- Draft questions to the applicant Members whenever the analysis of the dossiers identifies incomplete or unclear information;
- Submit to the SD the completed summary tables for each application together with possible questions for the applicant Members at least 10 days before the meeting and preferably by **18 September 2024;**

The SD will compile the summary tables and the questions to be forwarded to the applicant Members before the meeting. All subsequent information and material provided by a Member will be forwarded to the Group.

During the meeting

- Agree on the appointment of the Chair and Rapporteur of the meeting (the Chair will lead the discussion and the Rapporteur will ensure that the report reflects the discussion and captures the detailed assessment of the dossiers);
- Mention any potential conflict of interest and, if relevant, withdraw him/herself from the discussion;
- Contribute to the discussions;
- Provide a detailed report in order to recommend, to the Scientific Commission, the Member(s) or zone(s) to be recognised (or not) as having a controlled or negligible BSE risk status, indicate any information gaps or specific areas that should be addressed in the future by the applicant Members.

If during the meeting the Group decides that additional information should be requested from an applicant Member before an informed conclusion can be drawn, the SD can request it and forward the additional information to the Group at a later date. The Chair is responsible for coordinating the finalisation of the assessment and for ensuring that the views of all members of the Group are taken into consideration.

Should the Group not be able to complete its Terms of Reference during this meeting, experts' contributions will be solicited after the meeting, including by meeting if needed.

After the meeting

The SD will circulate the draft report after the meeting is over. Experts are expected to contribute to the finalisation of the report within approximately one week.

The SD will circulate the final version of the report to the Group once endorsed by the Scientific Commission and is published online.

Deliverables

A detailed report to recommend to the Scientific Commission whether an applicant Member(s) should be (or not) recognised with an official BSE risk status. The report should indicate any information gaps or specific areas that should be addressed in the future by the Members.

Reporting / timeline

WOAH will circulate the draft report no more than seven days after the meeting (no later than 14 October 2024) and the Group will finalise its report within ten days (indicative deadline: 25 October 2024).

Appendix 2 Agenda

***AD HOC* GROUP ON THE EVALUATION**

OF BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) RISK STATUS OF MEMBERS

1-4 October 2024

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1. Opening
2. Adoption of the agenda and appointment of Chair and Rapporteur
3. Evaluation of two applications from a Member for official recognition of zonal negligible BSE risk status
    - UK: Scotland
    - UK: England and Wales
4. Evaluation of the risk assessments of two Members already having an official negligible BSE risk status
    - China
    - India
5. Review of the meeting and working procedure (summary table)
6. Annual reconfirmation forms: supportive documented evidence and internal screening guidance for maintenance of official BSE risk status.
7. Any other business
8. Adoption of the report

Appendix 3 List of Participants

***AD HOC* GROUP ON THE EVALUATION**

OF BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) RISK STATUS OF MEMBERS

1-4 October 2024

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